

CLAIM STATUS

Claim 2 was previously cancelled. Claims 3, 13, 15, and 19 were previously withdrawn. Claims 1, 4-12, 14, and 16-18, and 20-22 are pending.

Claims 1 and 20-22 are currently amended. Specifically, claims 1 and 20-22 are amended to clarify that the tubular member (claims 1 and 21) or the second expandable stent (claims 20 and 22) have “a distal second expandable stent end and a proximal second expandable stent end.” Support for this amendment may be found throughout the specification, including FIGS. 1 and 2, which clearly illustrate that the tubular member or the second expandable stent have proximal and distal ends.

Claims 1 and 20-22 also recite that the tubular member (claims 1 and 21) or the second expandable stent (claims 20 and 22) can retain the tissue graft or the multilayered tissue graft construct, respectively, disposed on said first stent “solely by compressive forces.” Support for this amendment may be found throughout the specification, including for example at page 6, lines 1-3 and page 21, lines 1-4 where Applicants discuss that the diameters of *each of* the inner and outer expandable stents are selected to retain the tissue graft or the construct disposed on the inner stent and provide different compressive forces. Also, see page 6, lines 23-30 and page 7, lines 21-24.

Claims 1 and 20-22 are further amended to recite “wherein the distal and the proximal tubular member [or second expandable stent, as in claims 20 and 22] ends are substantially coincident with the respective distal and proximal first stent ends.” This limitation finds support in the specification, for example at page 4, last paragraph and page 11, lines 3-6 from the end of the page. Claims 1 and 20-22 are further amended to recite “during implantation and post-implantation of the prosthesis, the most distal tissue graft [or construct] end and the most proximal tissue graft [or construct] end remain substantially in the pre-implantation configuration such that the tissue graft [or construct] does not evert or fold into the passage of the first expandable stent.” Support for this amendment may be found throughout the specification including, for example, FIGS. 1 and 2; page 4, 1st and 2nd full paragraphs; page 21, lines 18-23.

No new matter has been added.

STATEMENT OF SUBSTANCE OF INTERVIEW

Applicants thank Examiner Prone for reviewing draft claims and the courteous and helpful telephonic interview on September 10, 2008 with Applicants' representatives, Janet Pioli and Magdalena Cilella. During the interview, proposed amended claim 1 and some of the references cited by the Examiner's under the obviousness rejection were discussed.

Applicants' representatives emphasized that proposed amended claim 1 further distinguishes Applicants' invention from the combination of U.S. Patent No. 5,865,723 to Love (Love) and U.S. Pat. No. 5,891,193 to Robinson et al. (Robinson et al.) because the combination of Love and Robinson et al. does not teach prostheses where the most proximal and most distal ends of the first stent are at least coincident with the ends of the tissue graft or the construct and where the proximal and distal ends of the tubular member or second expandable stent are substantially coincident with the respective proximal and distal first stent ends. The Examiner agreed that amendments to the claims along the lines discussed may receive favorable consideration however, a further search would be required. The amendments made herein are along the lines discussed with the Examiner.

Also, the Examiner suggested clarifying claim language of proposed claim 1 to avoid any new §112 rejections.

Applicants provide herewith amended claims, which are believed to overcome the remaining concerns of the Examiner.

**REMARKS RELATING TO THE FINAL
OFFICE ACTION DATED JUNE 24, 2008**

Rejection under 35 U.S.C § 103 – Obviousness

Summary

The Examiner issued a 35 U.S.C § 103(a) rejection of claims 1, 6, 9-11, 14, 17, 18 and 20-22 as being unpatentable over U.S. Pat. No. 5,865,723 to Love (Love) in view of U.S. Pat. No. 5,891,193 to Robinson et al. (Robinson et al.); rejection of claims 4, 5, 7 and 8 as being unpatentable over Love in view of Robinson et al. and further in view of U.S. Pat. No. 6,358,284 B1 to Fearnot et al. (Fearnot et al.); and rejection of claims 1, 12 and 16 as being unpatentable over U.S. Pat. No. 5,628,788 to Pinchuk (Pinchuk) in view of Fearnot et al.

Applicants respectfully disagree with the Examiner's rejections for reasons described below.

As amended claims 1, 2, 6, 9-11, 14, 17 and 18 are directed to stent tissue graft prostheses that include: (i) a first expandable stent having a first distal stent end and a first proximal stent end, a tubular wall and a passage extending longitudinally therethrough, (ii) a tissue graft having a distal tissue graft end and a proximal tissue graft end and disposed on said first stent, but not secured to said stent, and (iii) a tubular member having a distal tubular member end and a proximal tubular member end, a wall and a passage extending longitudinally therethrough, said tubular member being disposed over said tissue graft and around said first stent and retaining said tissue graft disposed on said first stent solely by compressive forces. In a pre-implantation configuration, a most distal end of the first distal stent end is at least coincident with a most distal end of the distal tissue graft end and a most proximal end of the first proximal stent end is at least coincident with a most proximal end of the proximal tissue graft end. During implantation and post-implantation of the prosthesis, the most distal tissue graft end and the most proximal tissue graft end remain substantially in the pre-implantation configuration such that the tissue graft does not evert or fold into the passage of the first expandable stent. The distal and the proximal

tubular member ends are substantially coincident with the respective distal and proximal first stent ends.

The amended independent claim 20 also is directed to a stent tissue graft prosthesis and differs from claim 1 by inclusion of a multilayered tissue graft construct.

Claims 21 and 22 are also generally directed to stent tissue graft prostheses. However, in claims 21 and 22, in a pre-implantation configuration, the most distal end of the first distal stent end of the prostheses *extends beyond* the most distal end of the distal tissue graft end (claim 21) or the construct end (claim 22) and the most proximal end of the first proximal stent end of the prostheses *extends beyond* a most proximal end of the proximal tissue graft end (claim 21) or construct end (claim 22) and where during implantation and post-implantation of the prosthesis, the most distal tissue graft end (claim 21) or the construct end (claim 22) and the most proximal tissue graft end (claim 21) or construct end (claim 22) remain substantially in the pre-implantation configuration such that the tissue graft (claim 21) or the construct (claim 22) does not evert or fold into the passage of the first expandable stent.

Argument for Claims 1, 6, 9-11, 14, 17, 18 and 20-22

The Examiner rejected claims 1, 6, 9-11, 14, 17, 18 and 20-22 as being unpatentable over Love in view of Robinson et al. Specifically, the Examiner asserted that although Love does not disclose that the distal and proximal most portions of the first stent are at least coincident with or extend beyond the distal and proximal most ends of the graft, Robinson et al. teach an inner expandable stent member having anchors that extend beyond the graft distal and proximal ends. The Examiner concluded that it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the implant of Love to have stent anchor extensions that extend beyond the graft ends as taught by Robinson et al. (1) to better anchor the implant to the vessel, and (2) the tubular implant taught by Robinson et al. is in the same field of endeavor.

As already asserted by the Examiner, Love does not teach Applicants' invention because Love does not disclose that the distal and proximal most portions of the first stent are at least coincident with or extend beyond the distal and proximal most ends of

the graft or the multilayered construct (Final Office action dated June 24, 2008 at page 2, second paragraph from the end). Robinson et al. do not cure the deficiencies of Love because Robinson et al. do not teach and provides no motivation or reason to modify the cited Love reference in order to arrive at the claimed prostheses inasmuch as neither of the applied references even acknowledges or recognizes that:

- 1) in a pre-implantation configuration, the distal and proximal ends of tissue graft or the multilayered construct need to be at least coincident with the ends of the inner stent (as in claims 1 and 20) or the distal and proximal ends of the first stent extend beyond the distal and proximal ends of the tissue graft or the multilayered construct, respectively (as in claim 21 and 22), where during implantation and post-implantation of the prosthesis, the most distal tissue graft or the construct end and the most proximal tissue graft or the construct end remain substantially in the pre-implantation configuration such that the tissue graft or the construct does not evert or fold into the passage of the first expandable stent, and
- 2) the distal and the proximal tubular member ends (claim 1 and 21) or the second expandable stent ends (claims 20 and 22) are substantially coincident with the respective distal and proximal first stent ends.

These teachings are only found in Applicants' disclosure and, in accordance with MPEP 2143, cannot provide the basis for a motivation to modify or combine references.

Applicants' invention of claims 1, 6, 9-11, 14, 17, 18 and 20-22 would not have been obvious in view of the Love and Robinson et al. references. Consequently, Applicants request that the 35 U.S.C § 103(a) rejection of claims 1, 6, 9-11, 14, 17, 18 and 20-22 as being unpatentable over Love in view of Robinson et al. be withdrawn.

Argument for Claims 4, 5, 7 and 8

The Examiner rejected claims 4, 5, 7 and 8 as being unpatentable over Love in view of Robinson et al. and further in view of Fearnot et al.

As discussed above, because (1) the Love reference does not teach Applicants' invention, (2) the Robinson et al. reference does not cure the deficiencies of Love, and (3) one of ordinary skill in the art would not have a reason to modify the prosthesis of

Love to have the inner stent and graft ends at least coincide, the invention of independent claim 1 would not have been obvious. Furthermore, the Fearnot et al. reference does not provide a reason to modify the prosthesis of Love to provide a prosthesis where

- 1) in a pre-implantation configuration, the distal and proximal ends of tissue graft need to be at least coincident with the ends of the inner stent, where during implantation and post-implantation of the prosthesis, the most distal tissue graft end and the most proximal tissue graft end remain substantially in the pre-implantation configuration such that the tissue graft does not evert or fold into the passage of the first expandable stent, and
- 2) the distal and the proximal tubular member ends are substantially coincident with the respective distal and proximal first stent ends.

Because the stent tissue graft prosthesis of Applicants' claim 1 is both novel and non-obvious, the prostheses defined by the claims depending on claim 1, are also novel and non-obvious. In particular, claims 4, 5, 7 and 8 are not obvious under 35 U.S.C. §103 over Love in view of Robinson et al. and further in view of Fearnot et al. Applicants request that the obviousness rejection of claims 4, 5, 7 and 8 be withdrawn.

Argument for Claims 1, 12 and 16

The Examiner rejected claims 1, 12 and 16 as being unpatentable over Pinchuk in view of Fearnot et al. Specifically, the Examiner asserted that "Pinchuk discloses invention substantially as claimed being a double-layered stent graft wherein the inner stent is smaller than the outer stent and the ends of each layer are at least coincident as seen in figures 3-9 [of Pinchuk]" (Final Office action dated June 24, 2008, page 4, lines 4-7). The Examiner further asserts that although the Pinchuk reference does not teach that the graft can comprise multiple layers of tissues, "Fearnot teaches the use of tubular grafts comprising layers of submucosa tissue sheets in the same endeavor for the purpose of providing enhanced repair of damaged or diseased host tissue" (Final Office action dated June 24, 2008, page 4, lines 6-10). The Examiner concluded that it would have been obvious to combine the submucosa tissue graft layers as taught by

Fearnot with the double layered stent graft of Pinchuk in order to provide enhanced repair of diseased host tissues and better anchoring and expansion.

Applicants disagree.

Neither the text of the specification nor the figures, including figures 3-9, of the Pinchuk reference teach or show stent tissue graft prostheses that include, in a pre-implantation configuration, a *first (inner) stent with ends that are at least coincident with the ends of a tissue graft*¹, where during implantation and post-implantation of the prosthesis, the most distal tissue graft end and the most proximal tissue graft end remain substantially in the pre-implantation configuration such that the tissue graft does not evert or fold into the passage of the first expandable stent. Also, neither the text nor the figures of Pinchuk teach that the distal and the proximal tubular member ends are substantially coincident with the respective distal and proximal first stent ends.

Although, in the Final Office action, the Examiner asserted that especially figures 5 and 6 of Pinchuk show that both the proximal and distal ends are at least coincident with the tissue graft, respectively, Applicants, again, point out that none of the figures of Pinchuk actually illustrate stent tissue graft prostheses where both, the proximal and distal ends of the inner stent are coincident with the ends of the tissue graft such that the tissue graft does not evert or fold into the passage of the first expandable stent. "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Specifically, figures 3-6 do not illustrate Applicants' prostheses. Rather, figures 3 and 4 of Pinchuk, as copies for Examiner's convenience below, illustrate a graft (textile tube) and figures 5 and 6 illustrate a stent graft; i.e., stent-over-graft).

¹ Applicants' arguments presented at pages 10-13 of Amendment and Response filed on April 25, 2007 together with a request for continued examination and after issuance of final Office action dated March 12, 2007, and arguments presented at pages 11-14 of Response to the Office action dated February 19, 2008 are incorporated herein by reference.

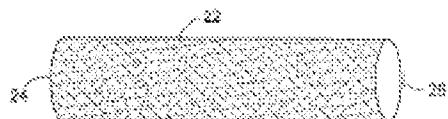


FIG. 3
GRAFT

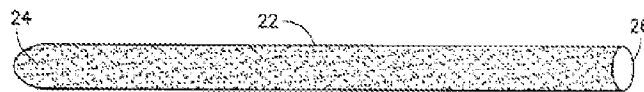


FIG. 4
GRAFT

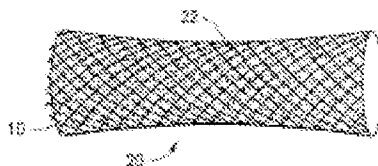


FIG. 5
STENT-OVER-GRAFT

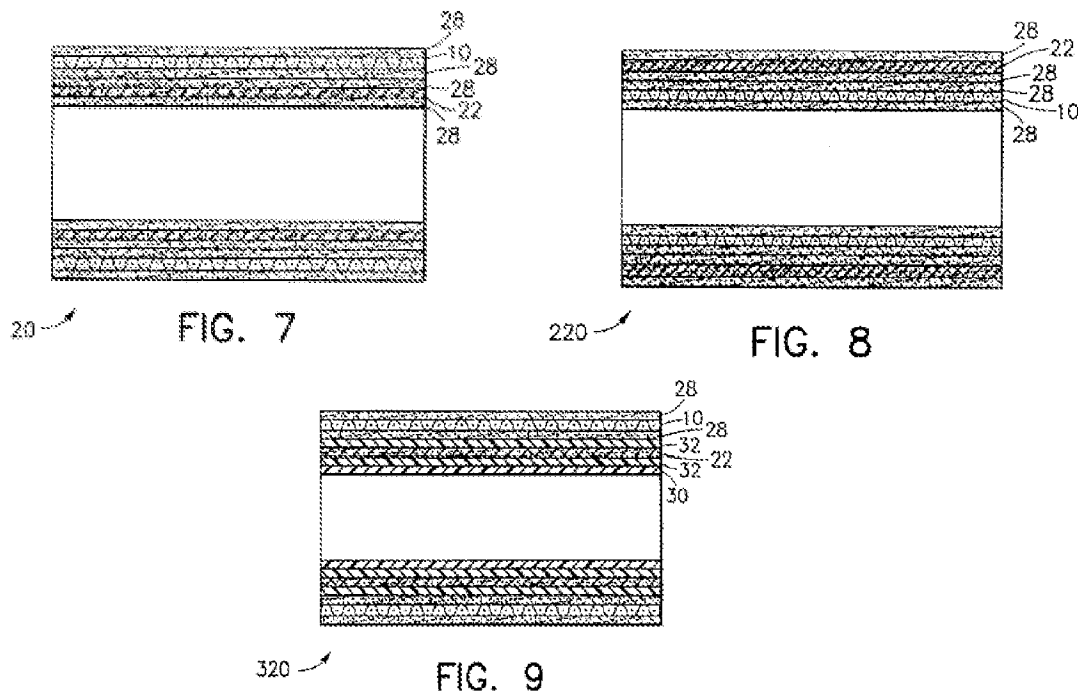


FIG. 6
STENT-OVER-GRAFT

It is clear that none of the figures 3-6 of Pinchuk show a two-stent device with tissue graft in-between. An inner stent is missing from figures 3-6 of Pinchuk. As such, the proximal and distal ends of the inner stent can not be coincident with the ends of the tissue graft simply because the inner stent is not taught in figures 3-6 of Pinchuk.

Similarly, figures 3-6 of Pinchuk do not illustrate that the distal and the proximal tubular member ends are substantially coincident with the respective distal and proximal first stent ends because the first (i.e., inner) stent is absent from these figures.

Furthermore, figures 7-9 of Pinchuk, which are copied for the Examiner's convenience below, do not show Applicants' invention. Rather, figures 7-9 of Pinchuk are cross-sectional views of various exemplary stent graft configurations and illustrate only small *portions* of the actual devices. Because there is no specific teaching in the text of the specification of Pinchuk that the ends of the inner stent 10 at least coincide with the ends of the graft 22, and figures 7-9 illustrate only small *portions* of the actual devices (rather than entire device), one of skill in the art would not conclude that figures 7-9 of the Pinchuk reference teach or suggest ends of the *inner* stent coinciding with the ends of the graft or suggest the distal and the proximal tubular member ends being substantially coincident with the respective distal and proximal first stent ends.



Although, the Pinchuk reference states that the inner stent may be included with the devices of some other figures, there is no teaching or suggestion whatsoever in the Pinchuk reference of ends of the *inner* stent being *at least coincident with the ends of the graft*. Clearly there is no teaching or suggestion whatsoever in the Pinchuk reference of all the elements of Applicants' claims 1, 12, and 16.

Furthermore, nothing in Fearnot et al. suggests modifying the prosthesis of Love or Pinchuk to include *an inner stent with ends that are at least coincident with the ends of a tissue graft* so that during implantation and post-implantation of the prosthesis, the most distal tissue graft end and the most proximal tissue graft end remain substantially in the pre-implantation configuration such that the tissue graft does not evert or fold into the passage of the first expandable stent, and so that the distal and the proximal tubular member ends are substantially coincident with the respective distal and proximal first stent ends.

In view of the above remarks, it would not have been obvious to one of skill in the art to combine the Pinchuk and Fearnot et al. references to arrive at the invention of claim 1. Because the stent tissue graft prosthesis of Applicants' claims 1 is both novel

and non-obvious, the prostheses defined by the claims depending on claim 1, are also novel and non-obvious. In particular, claims 12 and 16 are not obvious under 35 U.S.C. §103 over Pinchuk in view of Fearnot et al. Accordingly, Applicants request that the obviousness rejection of claims 1, 12 and 16 be withdrawn.

Conclusion

For the foregoing reasons, Applicants request that the 35 U.S.C § 103(a) rejection of claims 1, 6, 9-11, 14, 17, 18 and 20-22 as being unpatentable over Love in view of Robinson et al.; rejection of claims 4, 5, 7 and 8 as being unpatentable over Love in view of Robinson et al. and further in view of Fearnot et al.; and rejection of claims 1, 12 and 16 as being unpatentable over Pinchuk in view of Fearnot et al. be withdrawn.

SUMMARY

Applicants respectfully submit that the present application is now in condition for allowance. If, for any reason, the Examiner feels a discussion would expedite the prosecution of this application, the Examiner is kindly invited to contact the undersigned at (312) 245-5398.

Respectfully submitted,

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